

201 KAR 2:061. Procedures followed by the Kentucky Board of Pharmacy in the investigation and hearing of complaints.

RELATES TO: KRS 218A.205, 315.131, 315.191(4)

STATUTORY AUTHORITY: KRS 218A.205(3)(e), (f), (5), 315.191(1), (4)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations relating to the practice of pharmacy, including a process for complaints and hearings. KRS 218A.205(3)(e), (f), and (5) require the board to promulgate administrative regulations relating to complaints, licensure standards, and disciplinary actions. This administrative regulation establishes board procedure for investigations, the administrative hearings process, and the penalties for violations.

Section 1. (1) A complaint against a licensee may:

- (a) Be submitted orally or in writing; and
 - (b) Originate from a consumer, competitor, health professional, government or provider agency, or other interested party.
- (2) A complaint shall be accepted anonymously if the complaint is accompanied by sufficient corroborating evidence as would allow the board to believe, based upon a totality of the circumstances, that a reasonable probability exists that the complaint is meritorious.
- (3) A complaint shall not be required to be sworn to or notarized.

Section 2. (1) Except as provided by subsection (2) of this section, upon receipt of a complaint, the board shall instruct its staff to:

- (a) Conduct an investigation; and
 - (b) Report the conclusions and recommendations of the investigation to the:
 - 1. Executive director; and
 - 2. Board member assigned by the board to review conclusions and recommendations relating to an investigation.
- (2) If the complaint pertains to the improper, inappropriate, or illegal dispensing of controlled substances, the board shall:
- (a) File a report with the Attorney General's office, the Office of Inspector General's office, and the Department of the Kentucky State Police within three (3) business days;
 - (b) Commence an investigation within seven (7) days of the complaint; and
 - (c) Produce a charging decision within 120 days of the complaint, unless an extension for a definite time period is requested in writing by a law enforcement agency due to an ongoing criminal investigation.

Section 3. (1) A panel consisting of the assigned board member, the executive director, and the pharmacy drug inspector shall review the conclusions and recommendation relating to an investigation.

(2) The panel shall recommend one (1) of the following options to the board:

- (a) A reprimand restricting the licensee, permit or certificate holder;
- (b) The issuance of a formal complaint, order, and notice of hearing;
- (c) Dismissal of the case with or without prejudice; or
- (d) Returning the case to the inspector for further investigation.

(3) Documentation of a board reprimand shall be maintained in the appropriate board files.

Section 4. (1) With the approval of the board, the executive director shall notify the licensee, permittee, or certificate holder, in writing, that he or she may request an administrative confer-

ence before the executive director and the pharmacy drug inspector to be held prior to the hearing.

(2) The licensee, permit or certificate holder shall be notified that he or she may appear with counsel.

(3) An administrative conference shall be held to determine whether an agreement may be reached to resolve the complaint that is acceptable to all parties.

(4) If an agreement is reached, it shall be submitted to the board for approval and board order.

Section 5. (1) A settlement conference may be requested by the licensee, permit or certificate holder, or the attorney for that person.

(2) If a settlement conference is requested, it shall be scheduled. The settlement conference shall include the board's attorney, the licensee, permit or certificate holder, and the attorney for that person.

(3) If the parties to a settlement conference agree on stipulations, proposed terms, and conditions for an agreed order to resolve the complaint, they shall forward the agreed order to the board for approval.

(4) If the proposed agreed order is approved by the board, the complaint shall be considered resolved and a hearing shall not be held.

Section 6. Hearings. All hearings shall be conducted in accordance with the provisions of KRS 315.131(1).

Section 7. Posthearing Proceedings. (1) The board shall deliberate on all cases in closed session.

(2) Board counsel shall not attend, or be involved in any manner with, the closed session.

(3) The specific findings of the board shall be made in open session following the board's deliberation.

Section 8. Penalties. (1) Pursuant to KRS 218A.205(3)(e)1., a licensee convicted of a felony offense related to dispensing a controlled substance shall, at a minimum, be permanently banned from dispensing any controlled substance.

(2) Pursuant to KRS 218A.205(3)(e)2., the board shall impose restrictions short of a permanent ban from dispensing controlled substances on a licensee convicted of a misdemeanor offense relating to the dispensing of a controlled substance.

(3) Pursuant to KRS 218A.205(3)(e)3., a licensee disciplined by the licensing board of another state relating to the improper, inappropriate, or illegal dispensing of a controlled substance shall, at a minimum, have the same disciplinary action imposed in Kentucky as the disciplinary action imposed by the licensing board of the other state.

(4) Pursuant to KRS 218A.205(3)(f), the board shall submit all disciplinary actions to the National Practitioner Data Bank of the United States Department of Health and Human Services either directly or through a reporting agent. (18 Ky.R. 2449; Am. 2773; eff. 3-4-92; 39 Ky.R. 506; 1374; eff. 2-1-2013.)